

CLINICAL STUDIES

This chapter will discuss highlights of the groundbreaking Framingham Heart Study, as well as some research studies that have been completed on Bios Life™. This chapter is meant only to give an overview of these studies, as there are numerous studies ongoing. This chapter covers the following studies:

1. The Framingham Heart Study
2. The Cleveland Clinic Study
3. The Type-II Diabetes Trials
4. The Philippines Trial
5. The Utah Trial
6. The Pacific Rim Trial

Although not specifically related to Bios Life, it is important to discuss The Framingham Heart Study first. Begun in 1948, it is the longest ongoing study on heart disease. This will provide a basic understanding of cardiovascular disease and the findings resulting from this research.

1. The Framingham Heart Study

The relationship between the risk for cardiovascular disease (CVD) and cholesterol levels has been extensively researched. The most accurate data gathered from this research is the epidemiology study. In this type of study, researchers simply observe the cholesterol levels of a specific large group of individuals and then count how many cardiovascular events occur in a given time. That is exactly what has been done in the Framingham Heart Study, which began in 1948 under the direction of the National Heart, Lung, and Blood Institute (NHLBI).

The Framingham Heart Study, the most well known epidemiology study, has observed the population of the town of Framingham Massachusetts for a period of over 58 years. This ongoing study has included several generations of the town's population. Researchers have kept track of many parameters

and lifestyle habits of the inhabitants and their health concerns. In this way, the researchers have been able to relate certain diets, lifestyles, and blood parameters to the onset of disease.

As one can imagine, there is great mathematical and statistical talent needed to make the calculations necessary to connect the many variables to a specific disease. The outcome is often complicated and it is difficult to make generalized statements from the data. This study, however, concluded that high LDL (low-density lipoprotein) levels cause cardiovascular disease and that high HDL (high-density lipoprotein) levels protect against it.

A formula has been derived based on the study stating that:

- For every 1% one is able to lower LDL, there is a 2% risk reduction for CVD in the next 10 years.
- For every 1% increase in HDL, there is a 3% reduction in the risk for CVD.

It has therefore been concluded that in order to best lower the risk for CVD, one should both lower LDL and raise HDL at the same time. It is also important to note that the Framingham Study has found that no one who maintains total cholesterol below 150 has ever suffered a heart attack.

More detailed findings can be found on the FraminghamHeart Study website:
www.framinghamheartstudy.org

2. The Cleveland Clinic Study

Between the years 2000 and 2002, Bios Life was studied for its capacity to improve cholesterol levels by the Cleveland Clinic Foundation under the guidance of Dr. Dennis Sprecher. This institute has been recognized as America's number one Heart Center for 12 years in a row. No heart program has more experience, knowledge and better access to technology, and is therefore an ideal facility to confirm the effectiveness of Bios Life.

The study involved 119 patients that had a fasting LDL-c concentration of at least 130 mg/dL, making them moderate hypercholesterolemic (high blood cholesterol). The average age for the study participants was 50 years. The participants could not be using any medication to lower their cholesterol. The subjects were divided between two groups:

- A placebo group taking a non-active product
- A group using the fiber and vitamin portion of Bios Life™.

Before intervention began, both groups followed a low fat diet for eight weeks. This design was chosen to ensure similar dietary habits between the two groups. After the diet, both groups used their assigned products for a period of eight weeks. At the end of the study, 99 subjects completed the full protocol.

The Bios Life group:

- Reduced their LDL values from 159 mg/dl to 145 mg/dl on average, or a percent reduction of 7.9%
- HDL value increased from 48 mg/dl to 51 mg/dl over the eight week period
- Total cholesterol was reduced from 237 to 227 mg/dl, and triglycerides from 146 to 119 mg/dl

The placebo group:

- Showed an LDL increase of 2.4% in the same time period

In addition to lipid values, the study also monitored homocysteine and apolipoprotein B. Homocysteine, like high cholesterol, is recognized as a risk factor for cardiovascular disease. The mechanism is not entirely clear, but high homocysteine have been shown to increase injuries to the vascular system and contribute to early atherosclerosis. In this study, the homocysteine level was reduced from 9.8 mmol/l to 8.7 after eight weeks. Apolipoprotein B is a part of the LDL particle, and is therefore sometimes used as a surrogate marker for CVD risk. This parameter, also, was reduced from 139 to 110 mg/dl.

In conclusion, the Cleveland Clinic study showed that the fiber portion of Bios Life is effective in reducing the risk for cardiovascular disease. Since both groups started off with a low-fat diet, the overall effect of Bios Life may have been limited in this group. The subjects had already lowered their lipid parameters with diet alone. Consequently, the additional effect of Bios Life may have been more modest than by using subjects eating a more “normal” diet. The study was published in 2002 in the highly acclaimed journal, *Metabolism* (*Metabolism*, 2002, Vol 51: pp 1166 – 1170).

3. The Type-II Diabetes Trials

Bios Life’s mechanisms are designed to lower cholesterol, but they also interfere with carbohydrate (sugar) absorption in the gastrointestinal (GI) tract. Therefore, two studies at present have been performed with Type-II diabetics. Type-II diabetics are patients with low to zero response to insulin either from their body’s own production, or from injections.

The two studies were performed by Steven Freed and David Joffe, both registered pharmacists and editors of the worldwide known publication, *Diabetes in Control*. The first study, performed in the years 1999 to 2000, involved a small group of 15 patients that took the fiber portion of Bios Life for a period of 90 days. The protocol involved measuring HbA1c, glucose and cholesterol values, blood pressure, and weight at the beginning and end of the trial.

The pre-prandial glucose values (before the meal, at fasting) were reduced by 17% in the study period, indicating that the overall carbohydrate consumption during the day was lowered. The acute carbohydrate consumption was also reduced, as indicated by a 36% drop in the total glucose concentration two hours after the meal. Total cholesterol dropped 12%, triglycerides 42% and HDL increased 6%. In addition, the subjects lost an average of six pounds and were able to reduce their blood pressure from 145/82 mmHg to 131/77 mmHg, on average.

The drops in glucose absorption resulted in a HbA1c change from 9.2% to 7.8%. This value indicates the overall glucose level over the three month study, and is a powerful indicator of risk for

complications due to diabetes later in life, such as blindness, kidney failure, and the like. These results clearly demonstrate the glucose balancing effects of Bios Life™ and make a good case for daily use of Bios Life by diabetics. Since diabetics have even lower target values for cholesterol, the cholesterol effects of Bios Life are a potentially life saving side-benefit for this group. The study was published in *Diabetes in Control*, Issue 15 (1), 12 – 18 (2000).

Encouraged by these results, investigators initiated a second study in a much larger group of 78 Type-II diabetics using a similar study protocol. In this group, the average reduction in glucose values over a 90 day period was from 278 mg/dl to 237 mg/dl, resulting in a drop of 10% in the HbA1c value. Interestingly, LDL dropped 28.7% and HDL increased 27.9% in the study.

The study was presented at two major conferences: the 6th Annual Conference on Arteriosclerosis, Thrombosis and Vascular Biology, held in April 2005 in Washington D.C., and the 65th Scientific Sessions of the American Diabetes Association, held in June 2005 in San Diego, California.

The American Heart Association selected this study to be released to the press at this scientific meeting. International news agencies carried the press release.

4. The Philippines Trial

Bios Life has also been studied internationally. The first of such studies was performed in the Philippines by Dr. Norberto Yumul, M.D., from the Angeles Foundation Medical Center, in Angeles City, Philippines.

In this study, Dr. Yumul selected patients with dyslipidemia (abnormal blood lipid levels). One hundred and three subjects completed the four week intervention protocol. This was a mixed population, with approximately 22% of the group being diabetic. Some people had even suffered a myocardial infarction earlier in life.

Dr. Yumul analyzed the response to Bios Life in different age groups and gender. The overall result was that total cholesterol was reduced 15.8%. The study analyzed the results of LDL reduction in terms of the risk categories as formulated by the National Cholesterol Education Program. The main

conclusion was that for all age groups, subjects moved from the “undesirable” LDL group to the “borderline” group, and from the “borderline” group to the “desirable” LDL group.

Interestingly, the effect of Bios Life was more dramatic in the younger population (65 years or younger), providing additional evidence that Bios Life use should begin early in life so that the risk reduction effect is the greatest. The study was presented by Dr. Yumul at the 34th Annual Convention of the Philippine College of Physicians.

5. The Utah Trial

Since the development of Bios Life Complete with its four cholesterol lowering mechanisms, Unicity International performed a number of clinical trials with the new formulation. The first of these trials was performed in Utah, 2005.

For the study, a group of subjects was chosen randomly without regard to whether they had any cholesterol problems in particular (though many of them had, in line with the general population statistics). The average baseline LDL cholesterol value for the whole group was 131 mg/dl.

Twenty-five subjects completed the eight week protocol. They all took two packets of Bios Life per day. The average reduction in LDL cholesterol in eight weeks was 4.8%, reflecting the relatively young, healthy state of the participants. Interestingly, when looking at the responders in this group (responders denoting persons who demonstrated a positive result), the average reduction was 24.7%.

Seventy-two percent of the subjects were responders, indicating that the other 28% were likely not adequately compliant. The most important observation was that subjects with higher LDL levels at baseline had better results after eight weeks. Subjects with LDL levels of least 160 mg/dl at baseline reduced their cholesterol with 30.6% after eight weeks.

These statistics indicate the power of Bios Life as a first line treatment option for people with high cholesterol. HDL cholesterol was raised by 28.6% in the group of responding subjects with baseline levels lower than 40 mg/dl. These changes resulted

in a 24% drop in the cardiovascular risk ratio for the subjects having ratios higher than 5 at baseline.

For more information on the studies in this chapter, go to www.unicityscience.org/clinical

The results of this study are currently being considered for peer-review publication in a major scientific journal and are therefore not public yet.

6. The Pacific Rim Trial

Next in the journey of proving the efficacy of Bios Life™ is the study performed in the practice of Dr. Vincent Duenas. This study included both users and non-users of statin medication. The rationale for this design was to observe the effect of Bios Life as an adjunct to the cholesterol lowering effect of statin medication.

For the statin user trial, only subjects were selected that had reached the statin-floor, meaning that they did not have any change within 10% for their last two LDL measurements. This group of people was selected since it was prudent to exclude subjects still on the slope of LDL reduction due to statin intervention. Otherwise, the effects of using two products at the same time (statins and Bios Life) could make it impossible to determine which of the products was yielding the result.

The average LDL reduction of the 15 statin users in this trial with baseline levels of 130 mg / dl or higher was 21.1% in six weeks. For HDL, the increase was 23.3%. These results are considered impressive because they mean that even if one is taking statin medication, adding Bios Life will improve the risk for cardiovascular disease in addition to the effect reached by statins: an extra drop in LDL and a meaningful increase in HDL.

In particular, this last effect is valuable to statin users, since statins are not known to have any effect on HDL levels. The study was presented at the 7th Annual Conference on Arteriosclerosis, Thrombosis, and Vascular Biology in Denver in April 2006.

Summary

The important point to remember from this chapter is that Bios Life has been proven to be effective. It reduces LDL cholesterol, increases HDL cholesterol, and aids in regulating glucose levels in the body – and it does all this naturally, without negative side-effects.